RICHARD WOLF ellman

Surgitron

4.0 Dual RF/120 IEC

Instruction Manual

074-01-03

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I. INTRODUCTION

1.0 INTRODUCTION TO RADIOSURGERY

Surgery that is performed with modern radiosurgical equipment should not be confused with the results obtained with electrocautery, medical diathermy, spark gap generators, or partially rectified devices that do not provide surgical cutting waveforms. Thus, before reviewing the instructions and clinical use, a brief definition of radiosurgery and of the radiofrequency waves that produce this phenomenon may prove helpful.

Radiosurgery is an atraumatic method of cutting and coagulating soft tissue, without the post-op pain and tissue destruction of electrocautery. The cutting effect, known as **electrosection**, is performed without manual pressure or crushing tissue cells. It results from heat generated by the resistance the tissues offer to the passage of a radiofrequency wave, which is applied with a fine wire called a surgical electrode. The heat disintegrates and volatizes the cells in the path of the waves. This causes the tissue to split apart as though it had been cut with a razor-sharp knife. **Electrocoagulation** is a nonvolatilizing destruction of tissue cells by a radiofrequency wave.

The atraumatic nature of electrosection provides a noteworthy advantage. The lack of trauma results in tissue healing without fibrous contractile scar tissue, which characterizes healing of wounds created by manual cutting.

Radiosurgery, as a result of these advantages, facilitates, accelerates, and improves surgical procedures tremendously. It also helps to eliminate the unfavorable post-operative sequelae such as **swelling, infection,** and **postsurgical shock** from excessive blood loss, that are so often experienced after “traditional” instrumentation for comparable surgery.

1.1 SYMBOL DEFINITIONS

1.1.1 Classification = Class 1

1.1.2 Supply input power = 240V, 220V120V,100V~ 50/60 Hz.

1.1.3 Type BF defibrillator protection

1.1.4 Refer to manual

1.1.5 Protective earth connection

1.1.6 Neutral electrode referenced to ground

1.1.7 Fingerswitch control

1.1.8 Footswitch control

1.1.9 Neutral plate

1.1.10 Non-Ionization radiation

WARNING

Richard Wolf and ellman international strongly recommend the use of the **ellman** Corneal Eye Shield for any radiofrequency surgical procedure involving the eyelid and the immediate surrounding areas.

1.2	PACKING LIST	Wolf Part Number
1.2.1	**Wolf / ellman** Surgitron 4.0 Dual RF/120 IEC	2343.001
1.2.2	IEC Power cord	2343.903
1.2.3	Dual Footswitch & Cable	2343.901
1.2.4	IEC Foot Controlled Handpiece, 1/16" shaft	8792.698
1.2.5	Bipolar Cable	2343.837
1.2.6	Disposable Neutral Plate	2343.011
1.2.7	Instruction Manual	-
1.2.8	Three-Button Fingerswitch Handpiece	8792.696

OPTIONAL PARTS

1.2.9	Fingerswitch Handpiece 3/32" Shaft
1.2.10	Electrode Set 1/16" Shaft
1.2.11	Bipolar Forceps
1.2.12	Disposable Three-Button Fingerswitch Handpieces
1.2.13	Neutral Plate
1.2.14	Surgi-Cart III
1.2.15	Vapor-Vac II

II. TECHNICAL INFORMATION

2.0 DISTRIBUTOR'S INFORMATION

Richard Wolf Medical Instruments Corporation
353 Corporate Woods Parkway
Vernon Hills, Illinois 60061-3110
(800) 323-WOLF (9653)
sales&marketing@richardwolfusa.com

MANUFACTURER'S INFORMATION

ellman international inc.
1135 Railroad Avenue
Hewlett, New York 11557
(516) 569-1482

Manufacturer will make available on request circuit diagrams, component parts list, description, calibration instructions or other information necessary to assist the user's appropriately qualified technical personnel. Technical specifications subject to change without notice.

2.1 GENERAL DESCRIPTION

The **Wolf / ellman** Surgitron 4.0 Dual RF/120 IEC enhanced capability Radiosurgical Generator described herein is a compact source of high frequency low temperature RF energy to be employed for a variety of radiosurgery procedures. This action is achieved by front panel selection of waveforms and power levels. All selections are effected through push buttons and lamps which give the operator feedback of status. Power level for each mode is indicated by front panel digital displays which also show the status of self-test and monitoring. This display is interlocked with the controls to prevent operation when FAIL is displayed. The final output power control is made through foot and/or hand switches. An internal memory provides a special feature for the storage of all the front settings, mode and power output levels. Both Monopolar and Bipolar electrodes are available. This unit is designed to comply with international safety standards.

2.2 APPLICABLE SPECIFICATIONS

The following specifications are applicable to the extent called out herein.

IEC 60601-1	Medical Electrical Equipment - Part 1 General Requirements for Safety
IEC 60601-2-2	Medical Electrical Equipment - Part 2 Particular Requirements for Safety
UL 2601	Medical Electrical Equipment Safety (USA Version)
CSA 22.2601	Medical Equipment Safety (Canadian Version)

2.3 RF POWER OUTPUT

2.3.1 Output Level
The power output in the CW (CUT) mode is 120 watts into (500 ohm) a matched load.

2.3.2 Output Level Stability
The output is adjustable from less than 5W to maximum with little change in slope.

2.3.3 Power Output Stability
Impedance range of 50 ohms - 2K at any power setting or waveform setting.

2.3.4 Power Output Level Stability
Once enabled, the output remains constant within +/-10% turn on for a period of 10 seconds.

2.3.5 Power Output Purity
In the CW CUT mode harmonics and spurious are at least 20dB below the reference output for any load impedance in the range of 50 ohms to 2K ohms.

2.3.6 Frequency Accuracy
The output frequency is maintained at 4.0 MHz +/- 400Hz over all service and loading conditions including short and open for monopolar mode.

2.4 MODULATION (WAVEFORMS)
FOUR OUTPUT WAVEFORMS ARE PROVIDED.

2.4.1 CW CUT
Continuous wave output with average power equal to the maximum with no deliberate modulation.

2.4.2 CUT/COAG
Deeply modulated envelope with average to peak power ratio approximately 50%. Modulation occurring at 120 or 100 Hz rate.

2.4.3 HEMO
Deeply modulated square wave with average to peak ratio approximately 35% Modulation occurring at a 60 or 50 Hz rate.

2.4.4 FULGURATE
Deeply modulated wave with average to peak ratio to 10% or less. Modulation occurring at random rate but no greater than 1 KHz.

2.5 TIMING

The suggested operational duty cycle is 10 sec. ON/ 30 sec. OFF. The yellow indicator will be ON when CUTTING MODE circuit is energized. And the blue indicator will be ON when COAGULATION MODE circuit is energized. The unit will “beep” continuously when ON with a tone after 55 seconds of applied power at any level and in any mode. It shall change after 55 seconds and turn off after another 5 seconds.

2.6 CLASSIFICATION

2.6.1 According to the type of protection against electrical shock: the equipment is energized from an external electrical power source and is Class I equipment.

2.6.2 According to the degree of protection against electric shock: Type BF equipment.

2.6.3 According to the degree of protection against harmful ingress of water: ordinary equipment.

2.6.4 **Cleaning, Disinfecting and Sterilizing the Unit and Accessories**

2.6.4.1 Cleaning and Disinfecting the unit:
Cleaning and disinfecting of the unit should only be done with nonflammable and nonexplosive agents. Make sure that no moisture or detergents enter the unit. If

cleaning or disinfecting the unit with flammable or explosive agents is unavoidable, these must be completely evaporated from the HF Radio Surgical Generator before it is switched on.

ATTENTION: Alcohol must never be used to clean and disinfect the front panel. We recommend that the panel be disinfected by spraying or wiping. However, it is essential to follow the manufacturer's directions regarding cleaning, disinfecting and sterilizing of the accessories.

2.6.4.2 Handpiece and Electrodes

Cleaning:
Tissue residue can be removed from the active electrode with a sterile, moist cloth, steel or copper wool. No scalpel, scissors or similar pointed objects must be used for cleaning the electrodes, since they will damage the electrode surface. Such damage increases adhesion of tissue to the surfaces of the electrodes during use.

Disinfecting:
Always clean and disinfect the electrodes in a disinfecting solution prior to sterilizing them. All commercially available disinfectants may be used.

Sterilization:
Steam sterilize for 3 to 10 minutes for prevacuum, or gravity displacement (flash), at 132˚ to 135˚C (270˚ to 275˚F), 2.2 bar (32 PSI).

Disclaimer: All autoclavable products have an indefinite shelf life. These items should be routinely inspected for any wear, breaks, or deterioration of the insulation, and should be discarded and replaced if any of these common occurrences exist.

2.6.4.3 The dual footswitch is a waterproof unit, it can be cleaned with regular detergent.

2.6.5 The equipment is not suitable for use in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR OR WITH OXYGEN OR NITROUS OXIDE.

2.6.6 The mode of operation is continuous operation with intermittent loading, duty cycle 10 seconds on/30 seconds off.

2.6.7 The permissible operational environment conditions:

ambient temperature range	------ +10° C~ +40°C
relative humidity range	------ 30% ~ 75%

For transport and storage:

ambient temperature range	------ -10° C ~ +50°C
relative humidity range	------ 10%~95%
atmospheric pressure range	------ 500hPa~1060 hPA

This unit has been checked for proper and safe operation prior to shipment. However, all equipment should be rechecked for proper and safe operation prior to initial operation, and before each subsequent use.

2.7 PREVENTIVE INSPECTION AND MAINTENANCE

Regularly preventive inspection should be carried out to prevent reduced safety of the unit due to aging, wear and tear, etc. The cable and electrode must be checked before each use.

The **Wolf / ellman** Surgitron 4.0 Dual RF/120 IEC High-Frequency Radiosurgical Generator must be inspected for technical safety at least once a year. These technical safety inspections mean:

- Inspection of electrical safety in compliance with IEC 60601-1 and 60601-2-2
- Inspection for damage to the unit and its accessories
- Inspection of proper function of the unit

• Inspection of high-frequency output power in all of the modes

These technical safety inspections should be entrusted only to properly trained personnel. The manufacturer assumes no responsibility for improper changes or repairs carried out on the unit or its accessories by unauthorized persons, and the warranty of the unit expires immediately.

III. CAUTION AND WARNING

3.0 CAUTION AND WARNING

3.0.1 CAUTION: Do not use the Surgitron in the presence of flammable anesthetics or other flammable gases, flammable liquids, or flammable objects.

3.0.2 CAUTION: Electrical shock hazard. Do not remove cover. Refer to authorized personnel for service.

3.0.3 CAUTION: Surgitron may present a hazard to patients with pacemakers. Consult qualified medical personnel.

3.0.4 WARNING: Hazardous electrical output. This equipment is for use only by qualified personnel.

3.0.5 WARNING: Never increase the power settings without first checking both the active electrode and the neutral plate.

3.0.6 WARNING: The manufacturer-supplied accessories should be used to ensure the proper operation of safety monitoring circuit.

To ensure safe and reliable operation, the Surgitron unit and the relevant accessories should be checked for wear and tear before operation by qualified personnel.

A maintenance contract with the manufacturer or one of its authorized service agents is recommended after the warranty period.

3.1 SAFETY INSTRUCTIONS

Please review the below cautionary instructions to reduce the incidence of accidental burns.

3.1.1 The neutral electrode should be reliably attached with its entire area attached to the patient's body as close as possible to the operating field.

3.1.2 The patient should not come into contact with metal parts which are earthed or which have appreciable capacitance to earth. The use of antistatic sheeting is recommended for this purpose.

3.1.3 Skin to skin contact (for example, between the arms and the body of the patient) should be avoided.

3.1.4 When the Surgitron is used simultaneously with physiological monitoring equipment on the same patient, the monitoring electrodes should be placed as far as possible from the surgical electrodes. Needle monitoring electrodes are not recommended. Monitoring systems incorporating high-frequency current-limiting devices are recommended.

3.1.5 CAUTION: Interference caused by the Surgitron could adversely affect the operation of other electronic equipment.

3.1.6 The cables to the surgical electrodes should be positioned in such a way that contact with the patient or other leads is avoided. Temporarily unused active electrodes should be stored segregated from the patient.

3.1.7 For surgical procedures where the HF current could flow through parts of the body having a

relatively small cross-sectional area, the use of bipolar techniques may be desirable to avoid unwanted coagulation.

3.1.8 The output power selected should be as low as possible for the intended purpose.

3.1.9 Apparent low output or failure of the surgical equipment to function correctly at the normal operating settings may indicate faulty application of the neutral electrode or poor contact in its connection.

3.1.10 Do not use in the presence of flammable anesthetics.

3.1.11 Use only non-flammable agents for cleaning.

3.1.12 Flammable agents used for solvents of adhesive should be allowed to evaporate before application of the Surgitron. Any flammable fluid pooled under the patient or in the body depressions should be mopped up prior to using the Surgitron. Attention should be called to the danger of ignition of endogenous gases.

3.1.13 CAUTION: Some materials, for example cotton, wool, and gauze when saturated with oxygen may be ignited by sparks produced in normal use of the equipment.

3.1.14 CAUTION: Do not use on patients with pacemakers unless special qualified approval is obtained.

3.1.15 Before each use inspect the accessories, electrode cables and probes for possible physical damage.

IV. DESCRIPTION OF CONTROL ELEMENTS

4.0 SPECIAL FEATURE

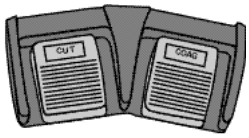
The **Wolf / ellman** Surgitron 4.0 Dual RF/120 IEC comprises some unique features which include: retractable mode and power output level setting, the waterproof dual footswitch for CUT and COAG modes, and a three-Button fingerswitch handpiece for CUT, CUT/COAG, and HEMO modes. The description is following:

4.0.1 MODE AND POWER OUTPUT LEVEL MEMORY

4.0.1.1 Mode and power output levels are stored in a non-volatile memory and recalled when the unit is turned on.

4.0.2 DUAL FOOTSWITCH AND THREE-BUTTON FINGERSWITCH HANDPIECE

4..0.2.1 Dual Footswitch:



A heavy duty waterproof dual footswitch for CUT and COAG modes. The footswitch mode selector and light indicators described in the section 4.2.7, 4.2.8, and 4.2.9 will respond accordingly to the activated mode. The yellow light indicator will be "ON" when the CUT footswitch is depressed. The blue light indicator will be "ON" when the COAG footswitch is depressed. The light indicators are normally OFF in this footswitch controlled mode since the mode selection (CUT or COAG) decision is made by the footswitch, i.e., the FOOTSWITCH MODE switch will not be in effect.

4..0.2.2 Three-Button Fingerswitch Handpiece:

This patented, unique fingerswitch handpiece is implemented to control CUT, CUT/COAG, and HEMO, three modes for delicate procedures. To activate this special function, depress the middle button on the Three- Button Fingerswitch Handpiece for three seconds. As the switch is held, the following sequences should be observed:

a. “HOLD” should be displayed on the power display of CUT mode.

b. The power display of COAG mode starts to count down from “3”, “2”, “1”, then “0”. Release the middle button.

c. Then, both power displays return to the previous power setting.

d. The blue light indicator is selected and "ON" for FOOTSWITCH MODE, which sets COAG mode in standby waiting for the action from the fingerswitch controller.

e. Yellow light (CUT) and (CUT/COAG) indicators will alternate "ON" and "OFF", they are in standby, ready for action from the fingerswitch.

f. Release the middle yellow button on the Three-Button Fingerswitch handpiece. The functions are successfully activated.

To adjust the power output for CUTTING MODE, the procedure is:

g. Depress the SELECT touch switch on the top yellow panel.

h. The "CUT" yellow light indicator stays "ON" instead of alternating with "CUT/COAG."

i. Adjust the power output by depressing the power-up or power-down push button to the desired power level for "CUT" mode.

j. Depress the SELECT touch switch on the top yellow panel again to adjust CUT/COAG power output, its yellow light indicator should be "ON" now.

k. Adjust the power output by depressing power-up or power-down push button for "CUT/COAG" mode.

l. During this power adjustment, the handpiece acts as two-button fingerswitch handpiece, thus the power output intensity may be tested.

m. Depress the SELECT touch switch again to reinstate the three-button fingerswitch function, yellow lights of (CUT) and (CUT/COAG) should alternate "ON" and "OFF" now, and the blue light of (HEMO) and (BIPOLAR) should alternate “on” and “off”.

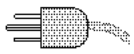
Regression:

The three-button fingerswitch handpiece may be used as a conventional two-button fingerswitch handpiece if the CUT/COAG mode is not activated. The Surgitron 4.0 Dual RF/120 IEC may be operated as unit to adopt an IEC two-button fingerswitch handpiece, if a three-button fingerswitch handpiece is not available.

4.1 THE REAR PANEL CONTROL ELEMENTS

see Figure 4.1 Rear Panel

4.1.1 Power Plug:

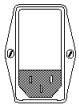


The Surgitron Unit is shipped with an approved hospital grade power connector. To ensure patient safety, the Surgitron unit must be properly grounded.

4.1.2 Power Socket:

The Surgitron unit must be connected to correctly installed sockets with a grounded earth conductor using the power cord supplied by the manufacturer.

4.1.3 Line Fuses:



The unit is protected with two line fuses. If a fuse blows, the unit should be checked for possible faults before the fuse is replaced and the unit is operated again. Always replace with a fuse of the same rating.

4.1.4 Audio Volume Control:

The volume of the acoustic signal should be set to a volume that can easily be heard by the user.

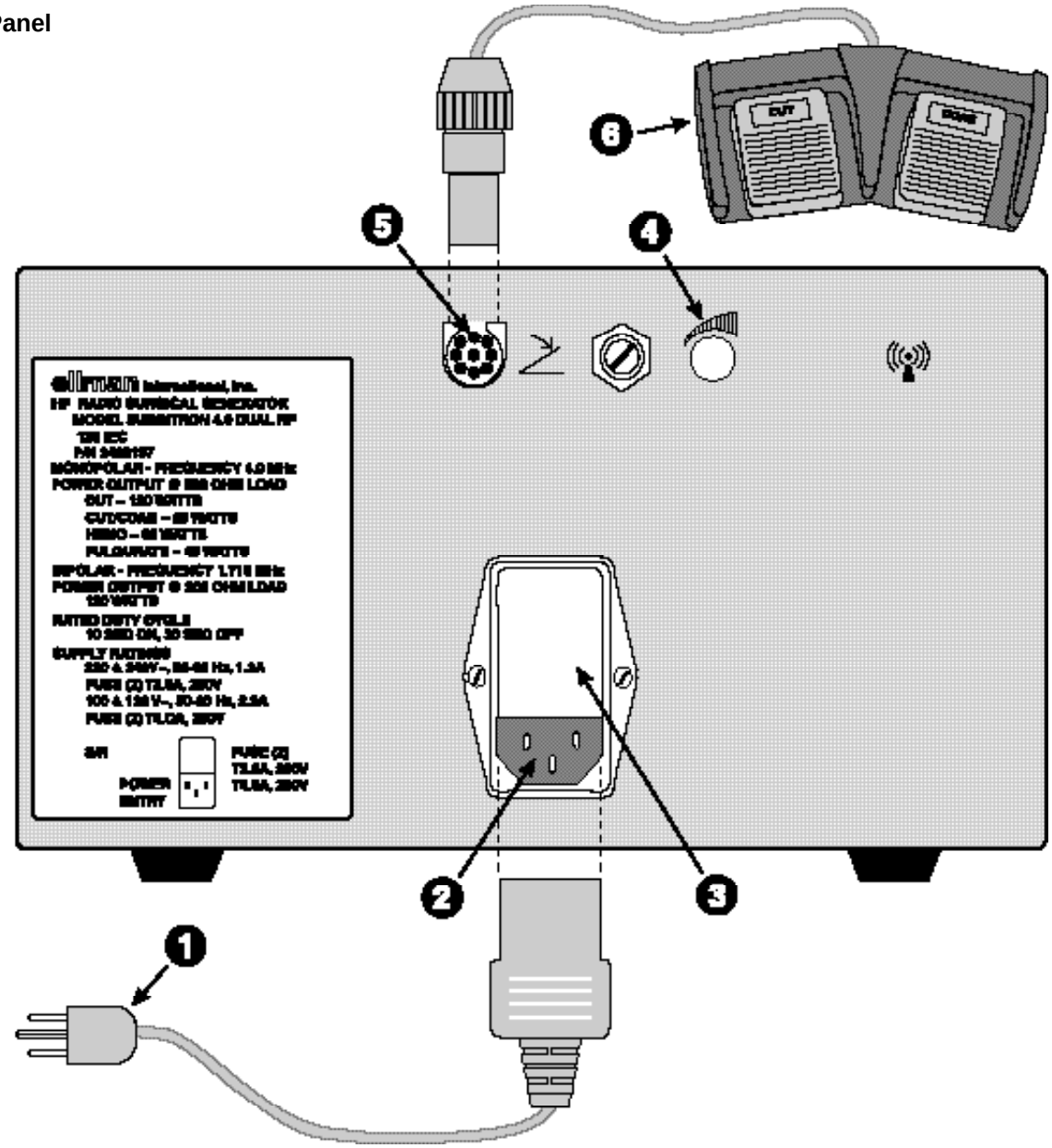
4.1.5 Footswitch Receptacle:

This 9-pin receptacle accepts a Hypersonics Footswitch connector.

4.1.6 Dual Footswitch Pedal:

The unit is shipped with a waterproof Dual Footswitch.

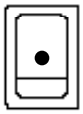
Figure 4.1
Rear Panel



4.2 FRONT PANEL CONTROL ELEMENTS

see Figure 4.2 for Description of the Front Panel Control Elements

4.2.1 Power Switch:



1

0

1 = ON

0 = OFF

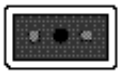
When the power switch is turned on, the unit always automatically performs the following function:

- The audio signal is activated after turning on the power switch.
- All start up sequences of tones on the front panel are activated automatically during the functional test. All front panel LEDS are activated.
- The patient return neutral plate is tested automatically. If the manufacturer provided neutral plate is not in place and not properly connected to the patient, the neutral optical signal will be Red and the audio alarm will be on until the patient return neutral plate is properly applied. The test is bypassed when the bipolar function is selected.
- All power digital indicators shall be at initial state -- “zero” shall be shown on both digital power indicators. If any error code is shown, the error must be cleared prior to using the equipment. *For error codes information, see 7.5 - Error Codes Table.*

4.2.2 Fault LED Indicator:

It will be Red if any error is detected, otherwise, it should be Green.

4.2.3 Neutral Plate Receptacle:



The neutral plate must be applied to the patient and connected to the equipment for monopolar techniques. This unit is equipped with a neutral plate safety monitor which monitors the electrical connection between a split-neutral plate and the unit, as well as between the split-neutral plates and the patient.

4.2.4 Neutral LED Indicator:

The indicator lights up Red and triggers an audible alarm if the neutral plate is not properly applied. The LED indicator will turn to Green when the neutral plate is correctly applied. This function is automatically bypassed if Bipolar mode is selected.

4.2.5 Bipolar Cord Receptacle:

Bipolar function can be activated by footswitch controller only.

4.2.6 Fingerswitch/Handpiece Receptacle:

Fingerswitch function may be applied on “CUT”, “CUT/COAG” (blend) and “HEMO” modes.
The Foot Control Handpiece may be used for modes “CUT”, “CUT/COAG”, “HEMO” or “FULGURATE” by depressing the appropriate pedal and adjusting the mode on the front panel.

4.2.7 Footswitch Mode Selector:

This mode selector is used to control the selection of CUT or COAG modes. However, in the advance Surgitron 4.0 Dual RF/120 IEC unit, this mode selector is controlled by a dual footswitch. *See section 4.0.1 for detail.*

4.2.8 Yellow Light Indicator:

The light indicator will be "ON" only when the "CUT" control footswitch pedal is depressed in Surgitron 4.0 Dual RF/120 IEC model.

4.2.9 Blue Light Indicator:

The light indicator will be "ON" only when the "COAG" control footswitch pedal is depressed in Surgitron 4.0 Dual RF/120 IEC model.

4.2.10 Cutting Mode Function Selector: (Select)

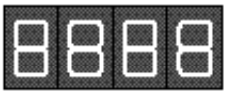
It is for selecting Cut or Cut/Coag functions. *See section 4.0.2. for Three-Button Fingerswitch Handpiece application.*

4.2.11 Yellow Light (Cut) **Indicator:**

The indicator illuminates when Cut function has been selected. *See section 4.0.2. for Three-Button Fingerswitch Handpiece application.*

4.2.12 Yellow Light (Cut/Coag) Indicator:

The indicator illuminates when Cut/Coag function has been selected. *See section 4.0.2. for Three-Button Fingerswitch Handpiece application.*

4.2.13 Output Power Intensity Indicator: 

The default state is zero when On/Off power switch is turned on. See section 4.0.1 for special features of the power storage. The output power will remain at the selected level unless it is changed . For true output power, see Figure Output Power Intensity vs. Power Setting. The number displayed indicates the relative power, which will be delivered to the patient when the mode is activated. *See section 4.0.2.2 for three-fingerswitch handpiece application.*

4.2.14 Power-up Push Button for Cutting Mode:

A single depression of the button switch increases the power setting by one. Continuous depression gradually increases the power to maximum - 100. *See section 4.0.2. for three-fingerswitch handpiece application.*

4.2.15 Power-down Push Button for Cutting Mode:

A single depression lowers the power setting by one. Continuous depression gradually decreases the power to minimum - "0." *See section 4.0.2. for Three-Button Fingerswitch Handpiece application.*

4.2.16 Coagulation Mode Function Selector: (Select)

It is for selecting Hemo, Fulgurate, or Bipolar function.

4.2.17 Blue Light Indicator: (Hemo)

The indicator illuminates when Hemo function has been selected.

4.2.18 Blue Light Indicator: (Fulgurate)

The indicator illuminates when Fulgurate function has been selected.

4.2.19 Blue Light Indicator: (Bipolar)

The indicator illuminates when Bipolar function has been selected.

4.2.20 Output Power Intensity Indicator for Coagulation Mode:

The default state is zero when On/Off power switch is turned on. See section 4.0.1 for special features of the power storage. The output power will remain at the selected level unless it is changed or the On/Off power switch is turned off. The number displayed indicates the relative power, which will be delivered to the patient when the mode is activated. For true output power, *see Figure Output Power Intensity vs. Power Setting.*

4.2.21 Power-up Push Button Switch for Coagulation Mode:

4.2.22 Power-down Push Button for Coagulation Mode:

4.2.23 Yellow Indicator:

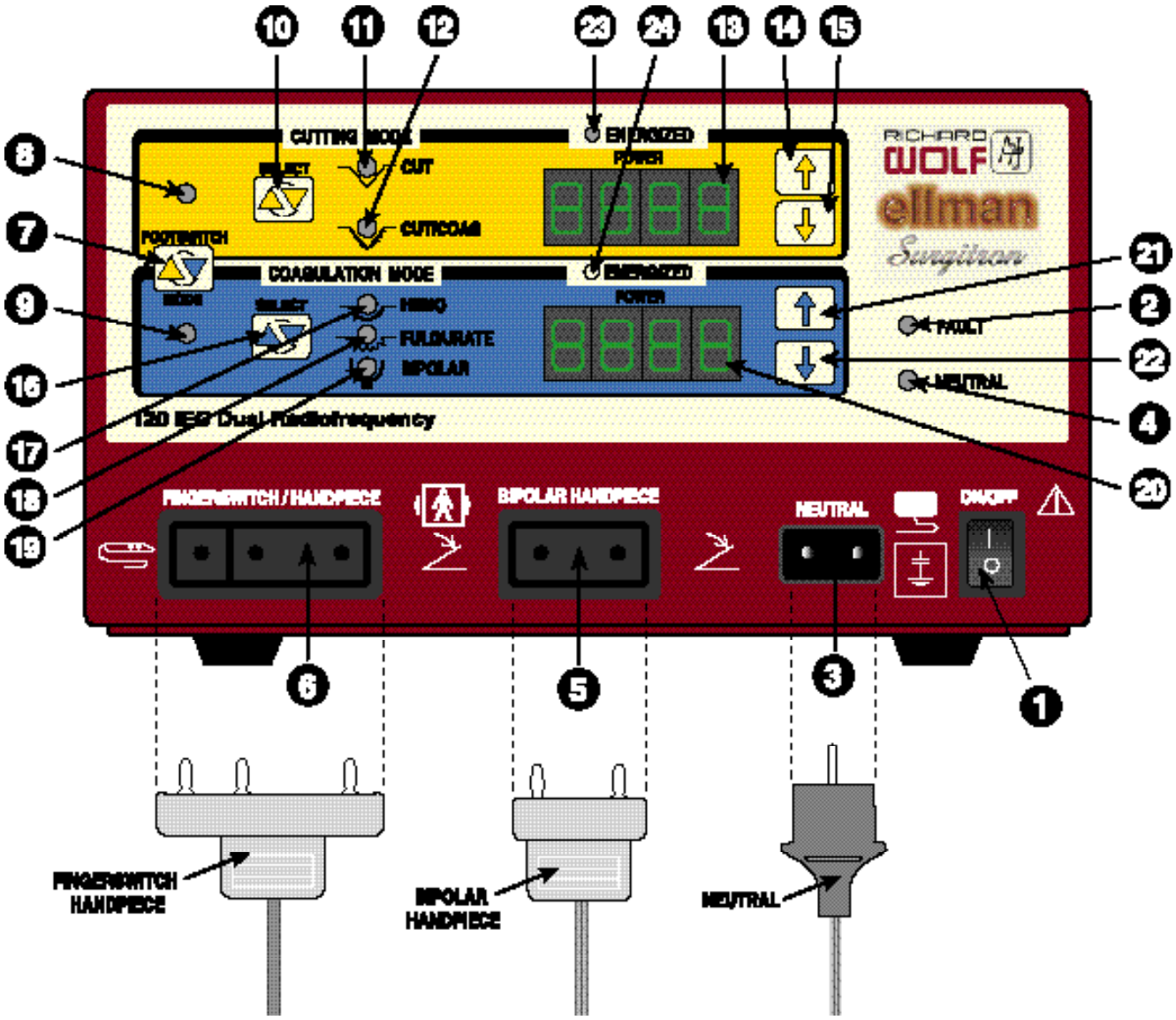
The Yellow indicator will be ON when CUTTING MODE circuit is energized.

4.2.24 Blue Indicator:

The Blue indicator will be ON when COAGULATION MODE circuit is energized.

NOTE: To guarantee against cross-contamination, the use of disposable electrodes and accessories is strongly recommended.

Figure 4.2
Numbers for Description of the Front Panel Control Elements



V. PREPARATION FOR USE

5.0 PREPARATION FOR USE

5.0.1 On the Surgitron 4.0 Dual RF/120 IEC check to make sure that the power switch is in the OFF position.

5.0.2 Connect the **Wolf / ellman** plug or IEC power cord set to a 3-wire ground AC power receptacle.

5.0.3 Insert the Handpiece male plug in the Handpiece receptacle on the front panel of the Surgitron 4.0 Dual RF/120 IEC marked “Handpiece”

5.0.4 Insert the Neutral Plate male plug into the neutral receptacle on the front panel marked “Neutral”

5.0.5 The Neutral Plate must make complete skin contact.

5.0.6 Select the correct electrode for the particular procedure to be performed. Insert the selected electrode into either the foot pedal activated handpiece or the Three-Button Fingerswitch activated handpiece. Select the handpiece of choice and plug into the receptacle on front panel.

5.0.7 Make sure that the electrode is seated fully so that no brass is exposed, and then turn chuck of handpiece clockwise until tight.

5.1 OPERATIONAL PREPARATION AND FUNCTIONAL SELECTION OF THE SURGITRON 4.0 DUAL RF/120 IEC

5.1.1 CUT - For pure micro-smooth cutting:

- Select "CUT" by pushing "SELECT" button on the Cutting Mode to turn on the CUT indicator.
- Push arrow button on the Cutting Mode to select the desired power level.
- Depress the "CUT" Footswitch controller or Three-Button Fingerswitch to activate the output power.

  (See section 4.0.2. for three-button fingerswitch handpiece application.)

5.1.2 CUT/COAG - For cutting with Coagulation:

- Select "CUT/COAG" by pushing "SELECT" button on the Cutting Mode to turn on the CUT/COAG indicator.
- Push arrow button on the Cutting Mode to select the desired power level.
- Depress the "CUT" Footswitch controller to activate the output power.

  (See section 4.0.2. for three-button fingerswitch handpiece application.)

5.1.3 HEMO - For pure Hemostatsis-Coagulation to control all forms of hemorrhage.

- Select "HEMO" by pushing "Select" button of the Coagulation Mode to turn on the "HEMO" indicatory light.
- Push arrow button on the Coagulation Mode to select the desired power level.
- Depress the "COAG" Footswitch controller to activate the output power.

  (See section 4.0.2. for three-fingerswitch handpiece application.)

5.1.4 FULGURATION - for desiccation or fulgurate spark-gap.

- Select "FULGURATE" by pushing "Select" button of the Coagulation Mode to turn on the "HEMO" indicatory light.
- Push arrow button on the Coagulation Mode to select the desired power level.
- Depress the "COAG" Footswitch controller to activate the output power.

  (See section 4.0.2. for three-button fingerswitch handpiece application.)

5.1.5 BIPOLAR - the Surgitron 4.0 Dual RF/120 IEC is equipped with Bipolar function to perform the Bipolar procedures:

- Insert the Bipolar male plug into the Bipolar Handpiece receptacle on the front panel.
- Select Coagulation Mode by selecting the desired power level.
- Depress the "COAG" Footswitch controller to activate the output power. This function can only be activated with the foot pedal.

VI. CLINICAL INFORMATION AND PRACTICING PROCEDURES

6.0 CLINICAL INFORMATION AND PRACTICING PROCEDURES

6.1 LEARNING TO USE RADIOSURGERY

Before making contact with the tissue, the power intensity must be selected and the Foot pedal or fingerswitch must be activated. During the actual cutting, it is important to use a smooth uninterrupted motion with even and light pressure. The movement should not be too slow. If it is, the build-up of lateral heat in the tissue may cause charring, followed by necrosis and sloughing (see Preoperative Cutting Practice). When performing a second or third cut in the same surgical site, allow approximately ten seconds for the tissue to cool between applications of the electrode to the site. Radiosurgery should not be regarded as a totally new art that will require learning of old skills. All rules of good surgical technique and clinical judgment still apply. The biggest difference, and **the most important thing to be learned** is that radiosurgery cuts **without pressure**, unlike the steel scalpel, and so a light, smooth, continuous brush-like stroke should be developed. Only then will the surgeon really appreciate the tremendous advantages inherent in radiosurgery.

6.1.1 Defining Good Technique

Radiosurgery can create tissue damage if the heat is allowed to accumulate in the tissue to the point where excessive dehydration occurs and the tissue is destroyed. Preventing the accumulation of such heat is the basic objective of radiosurgical technique. The accumulation of lateral heat in tissue depends upon various factors as indicated in the following formula:

$$\text{Lateral Heat} = \frac{\text{Time Which Electrode Contacts Tissue} \times \text{Intensity of Power} \times \text{Electrode Size} \times \text{Nature of Wave}}{\text{Frequency}}$$

This formula may be broken down in the following manner:

A. Electrode Contact Time
   a. The slower the passage of the electrode, the greater the lateral heat.
   b. The more rapid the passage of the electrode, the less the lateral heat.

B. Intensity of Power
   a. Intensity too high - high accumulation of lateral heat, due to sparking.
   b. Intensity correct - lateral heat reduced to the minimum necessary to volatize tissue cells. Smooth flow through tissue with no sparking and no resistance through tissue.
   c. Intensity insufficient - high accumulation of lateral heat due to drag. Also excess bleeding due to drag or tissue being pulled and torn from its base.

C Electrode Size
   a. The larger (or thicker) the electrode, the more lateral heat produced and the higher the power setting necessary to operate.
   b. The smaller (or thinner) the electrode, the less lateral heat produced and the lower the power setting necessary to operate

D Nature of the Waveform - *See Section 6.2 for details*
   a. Equivalent Fully Rectified Filtered (Continuous Wave - CW) - Least lateral heat.

b. Equivalent Fully Rectified - Low lateral heat.

c. Equivalent Partially Rectified - High lateral heat.

d. Equivalent Fulgurate Rectified - Highest lateral heat.

E Frequency - The higher the frequency, the less lateral heat produced.

6.2 WAVEFORM

6.2.1 Fully Filtered Wave - CW

The Fully Filtered Waveform is a pure continuous flow of high-frequency waves. This filtration results in a continuous non-pulsating flow of waves which provides a micro-smooth cutting flow. Under many clinical conditions, this feature is most advantageous. This wave produces the least amount of lateral heat and tissue destruction.

6.2.2 Fully Rectified Modulated Wave

The Fully Rectified Modulated Waveform produces a minute but perceptible pulsating effect which can, under certain conditions, slightly reduce the efficiency of the cutting effect. In addition to a smooth cut, the Fully Rectified Modulated Wave is accompanied by a very slight superficial coagulation on the raw cut tissue surfaces. When the tissue is areolar, a perceptible film of coagulum forms along the surface of the coated margins as the tissue heals. The coagulum does not interfere with normal healing by primary intention, and peels off spontaneously when the healing is complete.

6.2.3 Partially Rectified Modulated Wave

The Partially Rectified Modulated Waveform is an intermittent flow of the high-frequency waves in producing hemostasis, and it is highly effective in sealing off bleeders up to 1/16 inch in diameter eliminating the need to tie them off. The Partially Rectified Modulated Wave is also recommended for the indirect technique where one can coagulate blood vessels by grasping a hemostat and lifting free of surrounding tissues. An electrode is then brought into contact with the hemostat, 1 or 2 inches from its tips. When the Partially Rectified Modulated Waveform is turned on, the walls of the vessel will be sealed making ligation unnecessary.

6.2.4 Fulguration

The Fulguration or Spark-Gap Wave is a mutated electronic current that has been weakened to simulate the effects of the Oudin current. The Fulguration current produces a potent dehydration effect on tissues. Its destructiveness is self-limiting because of the air space the sparks must jump and because of the insulting effect of the carbon or eschar and the movement to prevent cumulative heat destruction.

6.3 PRE-OPERATIVE CUTTING PRACTICE

Since radiosurgery requires virtually no pressure to effect a cutting action, the hand should rest on some support in order to retain good control over the instrument. The ingredients for efficient radiosurgery are a gentle touch, digital dexterity, a fluid wrist action, and a feather-light touch. **The tissue to be cut should be moist. If it is too dry, surface charring will occur. Excessively dry tissue can most easily be moistened with a wet gauze.** Prior to performing an operative procedure, the area should be studied in order to select the correct electrode, waveform and power. **Several practice strokes, with power off,** are recommended to determine the correct length, depth, and direction of cut. Prepare the Surgitron 4.0 Dual RF/120 IEC for operations as described in **PREPARATION FOR USE**, then follow the steps below.

6.3.1.1 Select a piece of fresh, lean beef containing very little fat. Do not use veal because it does not change color when cut with an electrode. Allow meat to reach room temperature.

6.3.1.2 Place the meat on the Neutral Plate.

6.3.1.3 Insert the electrode of choice (Straight, Loop, Diamond or Vari-Tip) into the handpiece.

6.3.1.4 Select "CUT" by pushing "SELECT" button on the Cutting Mode to turn on the CUT indicator.

6.3.1.5 Set output to 90.

6.3.1.6 Depress the CUT Footswitch.

6.3.1.7 Using a smooth, brush-like motion, make several incisions of various lengths and depths. Then de-activate the electrode and observe the results. You will note that the power setting has been too high, causing sparking and noticeable discoloration along the cutting track.

6.3.1.8 Reduce the output power intensity to 10. You will notice the electrode either will not cut at all, or it will cut only with some pulling and dragging. Note, if cutting does occur, tissue shreds adhere to the electrode.

6.3.1.9 Repeat the above procedure for output power intensity settings of 70 to 80, etc., until such point when no discoloration occurs and there is no visible sparking. The radiosurgical tip should not encounter resistance. The cut should be micro-smooth without sparking and without drag. These results normally occur at an output power of 20 to 50. Continue to practice using slow, medium, and fast cutting strokes at each of the settings to acquire the dexterity and confidence required for an actual operation on a patient.

6.3.4 Pre-Operative Coagulation Practice

Surgitron 4.0 Dual RF/120 IEC can be used to seal off small blood vessels. Move to the HEMO mode (Partially Rectified Wave). The ball electrode is normally used since it provides extended coverage of the tissue surfaces. Prior to performing Coagulation, the tissue should be wiped clean of blood so that the area needing treatment can be viewed. Direct pressure will help to locate bleeders. Intermittent gentle contact with the tissue is performed until bleeding stops. The same meat specimen used for cutting may be used for coagulating practice. Effective coagulation is achieved when the treated area appears on the meat as blanched spot of approximately 2 mm diameter with a minimum penetration into the tissue. Feather-light touching of the ball electrode is all that is necessary to coagulate bleeders efficiently

6.3.4.1 Place the beef on the Antenna Plate.

6.3.4.2 Insert the ball electrode into the Handpiece.

6.3.4.3 Set the output power intensity to 10.

6.3.4.4 On the Surgitron 4.0 Dual RF/120, set to “HEMO”.

6.3.4.5 Position the ball electrode in light contact with the beef.

6.3.4.6 Depress the “COAG” Footswitch or the blue button on the Three-Button Fingerswitch Handpiece.

6.3.4.7 Repeat the above procedure with power settings of 20, 30, & 40. Contact should be 2 to 3 seconds.

6.3.4.8 Switch to the OFF position to disconnect power.

6.3.5 Control of Bleeding - HEMO

Abnormal bleeding is not a problem in radiosurgery. A wide range of coagulation or hemorrhage control can be obtained by utilizing the partially rectified modulated wave with different techniques. All forms of hemorrhage must be stopped first by some form of direct pressure - air, compression, or hemostat. When bleeding has momentarily stopped, final sealing of the capillaries or large vessels can be accomplished by brief application of the partially rectified modulated waveform. There are two types of hemo electrodes: ball electrodes, and thick needle electrodes.

6.3.6 Bipolar

The Surgitron 4.0 Dual RF/120 IEC can be used for bipolar coagulation procedures. The power should be lowered to 10 or 20 depending on the procedure.

6.3.7 Electrode Sterilization

The active part of the electrode is always sterile when the Surgitron is in operative use. The tissue will also be sterilized when it comes in contact with the active electrode. This is an extreme advantage over the scalpel, which is contaminated by the nonsterile tissue surrounding the surgical incision. The shank of the electrode, however, is not sterilized when the Surgitron is activated. It is, therefore, suggested to either autoclave the electrodes or cold sterilize them. The electrodes will have longer shelf life if they are cold sterilized. Do not attempt to operate with electrodes if the protective insulation is cracked or worn. In the event that the brass is exposed, a shock or burn may be felt by the operator or patient.

6.4 ANESTHESIA

Anesthesia, either local or general, must be used with radiosurgical procedures. IF NITROUS OXIDE analgesia is used, a local anesthetic should also be used.

VII. TECHNICAL SPECIFICATIONS

7.0 TECHNICAL SPECIFICATIONS

7.1 OUTPUT CHARACTERISTICS

Mode/ Character	Output Waveform	Maximum Output Power	Power Output vs. Setting	Power Output vs. Load Resistance	Activation
Cut	4.0 MHz CW sinusoid	120W @ 500 Ω	See Figure 8.1	See Figure 8.2	via foot pedal or fingerswitch
Cut/Coag	4.0 MHz with rectified full-wave envelope	80W @ 500 Ω	See Figure 8.1	See Figure 8.3	via foot pedal or fingerswitch
Hemo	4.0 MHz with square wave rectified envelope	60W @ 500 Ω	See Figure 8.1	See Figure 8.4	via foot pedal or fingerswitch
Fulgurate	4.0 MHz with modulated	40W @ 500 Ω	See Figure 8.1	See Figure 8.5	via foot pedal or fingerswitch
Bipolar	1.7 MHz with 1/2 wave rectified envelope	120W @ 200 Ω	See Figure 8.1	See Figure 8.6	via foot pedal

NOTE: The open-circuit Output peak-to-peak Voltage for all modes is approximately 1,000 Volts.

7.2 SAFETY FEATURES

All waveforms are interrupted at a 37 Hz. rate to allow sampling with the power off.

7.2.1	Standard Compliance	IEC60601-1 IEC60601-2-2
7.2.2	Neutral Plate Electrode	earthed at HF
7.2.3	Neutral Electrode monitor resistance between the 2 contact areas of a split neutral electrode	MAX 1000 ohms

7.2.4	Alarm when resistance between the contact areas of a split neutral electrode is 1000 ohms or greater	red signal indicator and audio alarm
7.2.5	Continuous temperature monitor If temperature rises above 85°C during operations the unit will declare an error message	- error code 12
7.2.6	Continuous power test/monitor output power	Error code 13 if power test failed
7.2.7	Error indication after self check	Refer to listing of error codes
7.2.8	Defined duty cycle protection	10 sec. on active time/30 sec. off

7.3 INPUT CHARACTERISTICS

7.3.1	Nominal line voltage	240V, 220V120V,100V ~ ± 10%
7.3.2	Line frequency	60 Hz./50 Hz.
7.3.3	Power consumption at max. output power	330 VA
7.3.4	Input current at max output power	1.30A
7.3.5	Rating of fuses in the main supply power	T 2.0A, 250V, Two

7.4 SIZE AND WEIGHT

7.4.1	W x H x D	9” x 5” x 13”
7.4.2	Weight	18 lbs.

7.5 ERROR CODES TABLE

DESCRIPTION	ERROR CODE
Interface to displays failed	1
Interface to LEDS failed	2
Interface to keypad failed	3
Processor had a warm reset	4
A/D converter error	7
Foot/Fingerswitch interface failed	8
Bond sensor interface failed	9
Keypad pressed during power up protection failed	10
Foot or Fingerswitch pressed during power up protection failed	11
Temperature out of limits	12
Output power test failed	13
Linearization Table in Error	15
EEPROM Read	16
EEPROM Write	17

NOTE: All error messages will be reset by turning the unit off and correcting the condition.

VIII. FIGURES

8.0 POWER OUTPUT CHARACTERISTICS

8.1 POWER OUTPUT VS. DIGITAL SETTING (500 Ω RESISTIVE LOAD)

8.2 CUT MODE POWER OUTPUT VS. RESISTIVE LOAD

8.3 CUT/COAG MODE POWER OUTPUT VS. RESISTIVE LOAD

8.4 HEMO MODE POWER OUTPUT VS. RESISTIVE LOAD

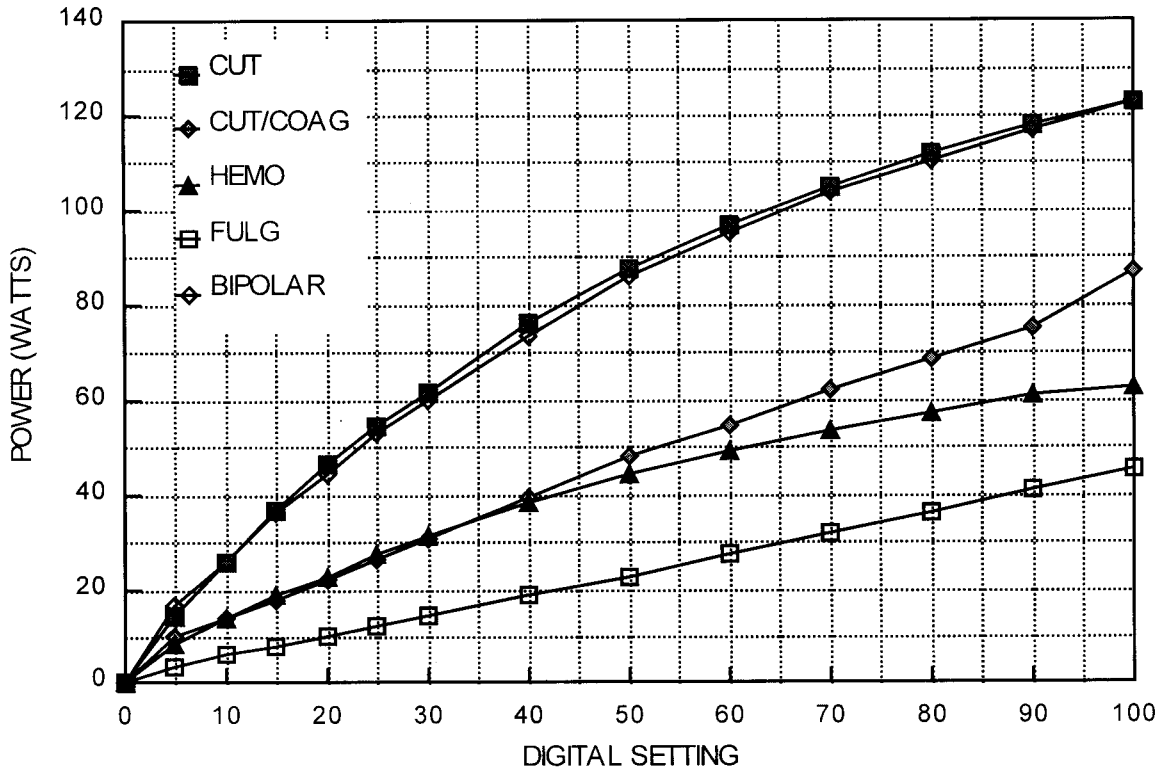
8.5 FULGURATE MODE POWER OUTPUT VS. RESISTIVE LOAD

8.6 BIPOLAR MODE POWER OUTPUT VS. RESISTIVE LOAD

SURGITRON 4.0 DUAL RF/120 IEC
MONOPOLAR AND BIPOLAR MODES

Figure 8.1 - Power Output vs Digital Setting

Monopolar 500 Ohms(Bipolar 200 Ohms) Resistive Load

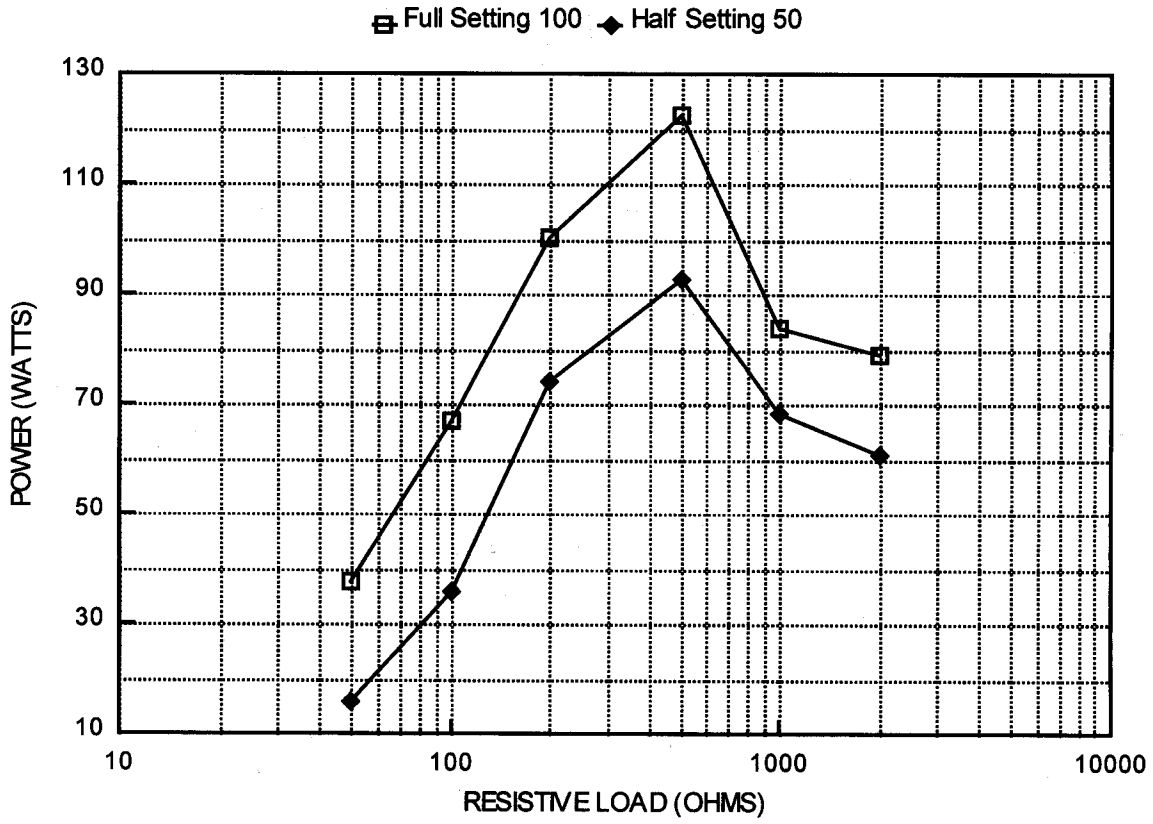


NOTE:

The above power chart is a typical output characteristic of the **Wolf / ellman** Surgitron 4.0 Dual RF/120 IEC unit. Actual output power measurements may vary with type of test equipment used and method of circuit connection. The actual power as a function of load resistance and output control setting shall not deviate by more than +/-20%

SURGITRON 4.0 DUAL RF/120 IEC
CUT MODE

Figure 8.2 - Power Output vs Resistive Load



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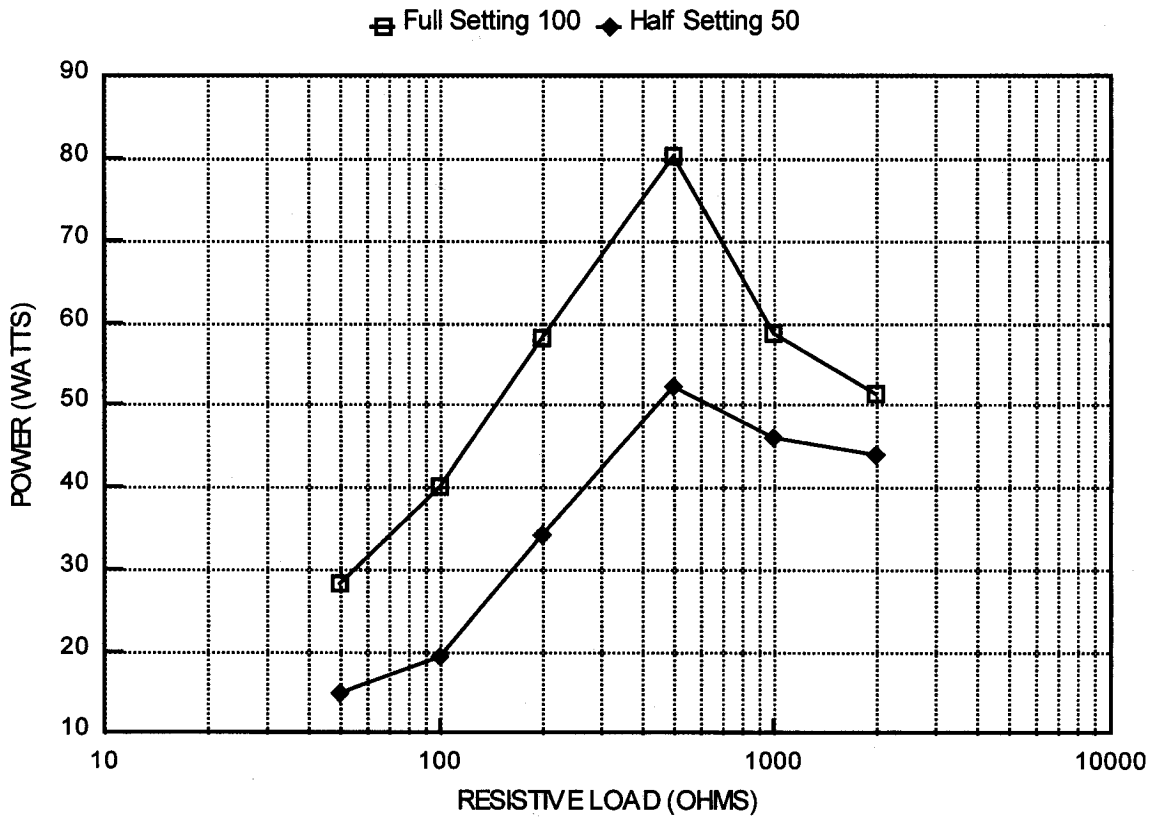
SURGITRON 4.0 DUAL RF/120 IEC
CUT/ COAG MODE

Figure 8.3 - Power Output vs Resistive Load



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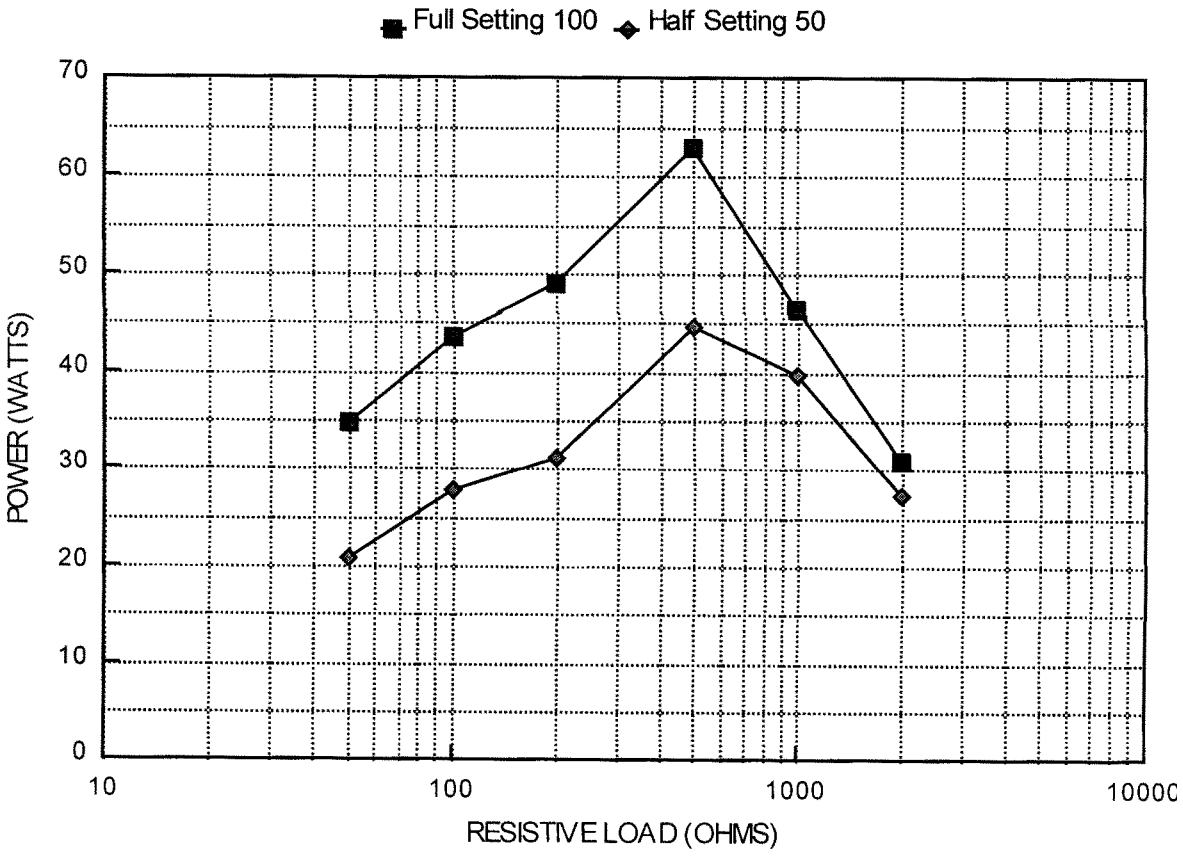
SURGITRON 4.0 DUAL RF/120 IEC
HEMO MODE

Figure 8.4 - Power Output vs Resistive Load



NOTE:

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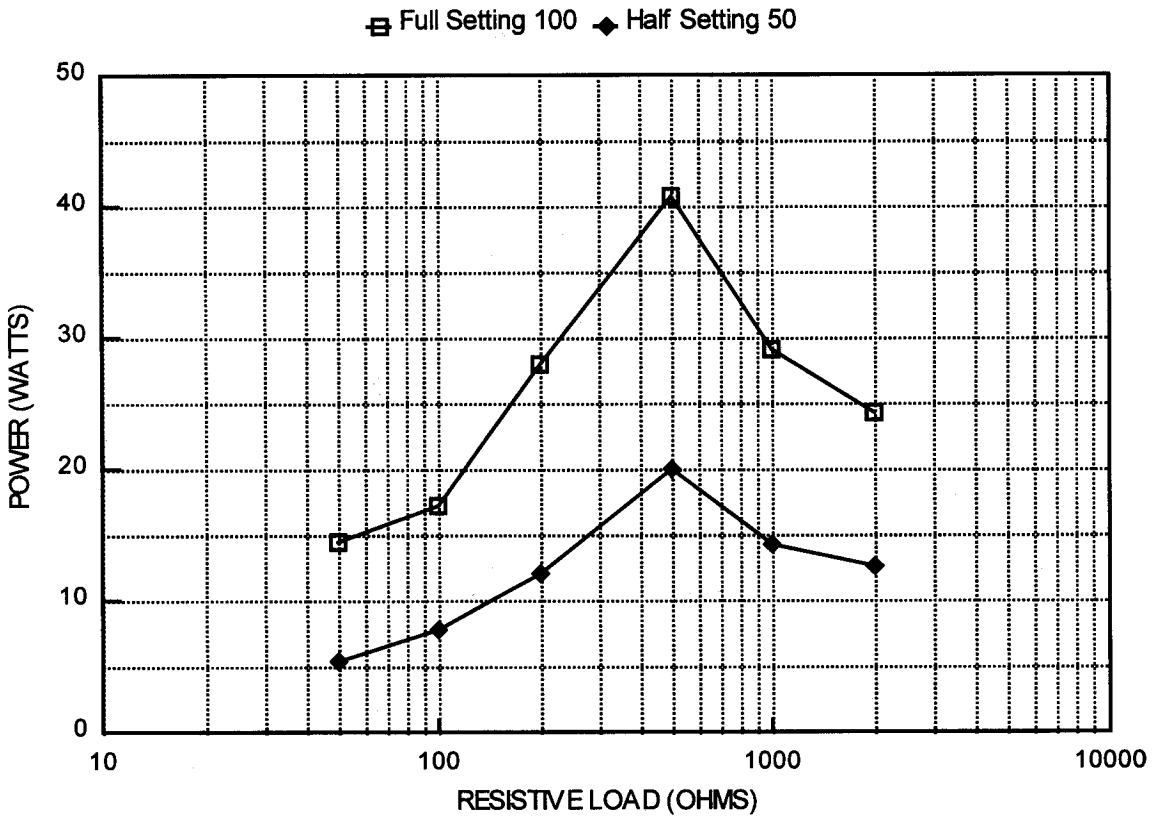
SURGITRON 4.0 DUAL RF/120 IEC
FULGURATE MODE

Figure 8.5 - Power Output vs Resistive Load



NOTE:

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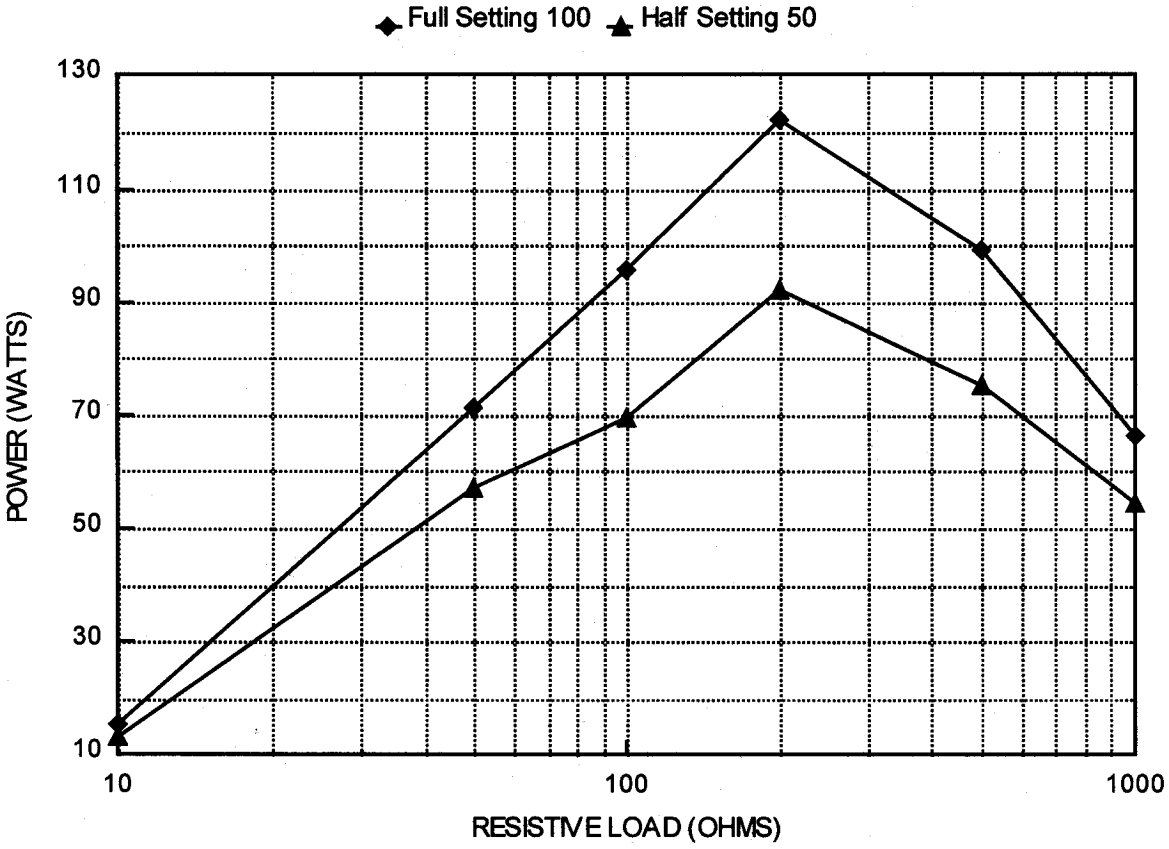
SURGITRON 4.0 DUAL RF/120 IEC
BIPOLAR MODE

Figure 8.6 - Power Output vs Resistive Load



NOTE:

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